

REMARKS

Prior to this Supplemental Response, Claims 1, 3-5, 8-9, 11, 14 and 21 were pending. The pending claims relate to a device for delivery or release of a substance into a vaginal cavity. Applicants amend Claims 1, 3-5, 8-9, 11, 14 and 21 and add new Claims 22-32. The amendments and the new claims do not add any new matter. Claims 1, 3-5, 8-9, 11, 14 and 21-32 will be pending after entry of this Supplemental Response.

Support for the Amendments

The claim amendments and the new claims are supported throughout the application, as filed. Support for the amendments to Claims 1, 8 and 21 and new Claims 25 and 29 is found in the specification, for example, on page 5, lines 13-21, page 8, lines 15-19, page 9, lines 3-4, page 11, lines 6-7. Support for the amendments to Claim 3 and new Claim 22 is found, for example, on page 9, lines 4-7. Support for new Claim 23 is found, for example, on page 7, lines 3-4. Support for new Claim 24 is found, for example, on page 7, lines 11-12. Support for new Claims 26-28 is found, for example, on page 5, lines 9-15. Support for new Claims 30-33 is found, for example, on page 9, lines 14-15 and page 12, lines 1-2. Applicants also amend the claims for clarity and consistency.

Interview Summary

Applicants thank the Examiner for extending the courtesy of an in-person interview on August 18, 2009 ("interview"). In attendance at the interview were Examiner Gilbert, Dr. Elena Polovnikova (Applicant's agent of record) and Dr. Stan Alkemade (the representative of the Assignee of the present patent application, Bioniche, Inc). Those in attendance discussed the differences between the claimed embodiments of applicants' device and the nose clip disclosed in U.S. Patent No. 4,369,783 to Hiller *et al.* ("Hiller"). The *Remarks* section of the previously filed Response formed the basis of the discussion. Those in attendance also discussed potential claim amendments to clarify the differences between the claims and the Hiller nose clip. An agreement

was reached that Applicants would submit a supplemental response. Certain claim amendments discussed during the interview are incorporated into the amendments of independent Claims 1 and 21, submitted in this Supplemental Response.

Rejections under 35 U.S.C. §102(b)

The Examiner rejects Claims 1, 4-5 and 8 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,369,783 to Hiller *et al.* ("Hiller"). Applicants respectfully assert that Hiller fails to anticipate Claims 1, 4-5 and 8 at least based on the remarks on page 7-8 of the previously filed response and further in view of the amendments to Claims 1 and 21 in this Supplemental Response.

To facilitate allowance, Applicants amend independent Claim 1 to recite "a distal section of each of the at least two resilient arms ... tensioned outwards from a central section of the support frame towards a mucosal membrane of the vaginal cavity when the device is *in situ*, wherein the outwards tensioning retains the internal substance delivery device within the vaginal cavity and against the mucosal membrane of the vaginal cavity when the device is *in situ*." Applicants amend independent Claim 21 to recite "at least two resilient arms tensioned outwards at or near a distal end, the tensioning engaging the intra-vaginal release device within the vagina when the device is *in situ*, ... wherein each distal end of the at least two resilient arms and pods attached to the arms extend outward from a central section of the support frame towards the mucosal membrane of the vagina when the device is *in situ*." Applicants assert that Hiller fails to anticipate Claims 1 and 21 at least because it fails to teach or suggest at least some of the elements recited above. Hiller therefore fails to teach each and every element of the claims as required for anticipation in MPEP 2131.

Applicants respectfully assert that, in contrast to the device recited in the currently amended claims, even if the nose clip disclosed in Hiller were to be placed into a vaginal cavity, as the Examiner proposed in the Office Action, the inwardly turned distal parts, sections, or ends of the arms of nose clip would not be tensioned outwards, thereby retaining or engaging it

against the surrounding vaginal walls. Applicants further assert, upon placement into the vagina, the inwardly turned distal ends of the Hiller nose-clip and the attached, also inwardly turned, terminal means would not extend outward towards the mucosal membrane of the vagina, as recited in currently amended Claim 21. The terminal means of the Hiller nose clip are turned inward, facing each other, as required for clamping against the nasal septum during the intended use of the nose clip. Therefore, none of the terminal means would be in contact with the walls of the vagina, in contrast to at least one of the pods recited in Claim 21.

Due to at least the reasons discussed above, Applicants respectfully submit that Hiller fails to anticipate the pending claims. Applicants request withdrawal of the rejection under 35 U.S.C. §102(b).

Rejections based on 35 U.S.C. §103(a)

The Examiner rejects Claim 11 under 35 U.S.C. §103(a) as obvious over Hiller, asserting that Hiller discloses Applicants' invention substantially as claimed, except for expressly disclosing the support frame made of nylon. The Examiner rejects Claims 3, 9, 14 and 21 as under 35 U.S.C. §103(a) as obvious over Hiller in view of U.S. Patent No. 5,816,248 to Anderson *et al.* ("Anderson"), which discloses a vaginal insert for delivering an agent to urogenital tract of a patient. Applicants respectfully assert that Hiller or a combination of Hiller and Anderson fail to render obvious the rejected claims at least in view of the remarks submitted on pages 7-9 or the previously filed Response and further in view of the amendments to independent Claims 1 and 21 submitted in this Supplemental Response.

Applicants assert that modifying the device in Hiller with a nylon support frame, as proposed by the Examiner, would not result in the device recited in Claim 11 at least due to the differences between the claims and the device disclosed in Hiller, as discussed in the previously filed Response and in the previous section of this Supplemental Response. Applicants therefore assert that Hiller fails to render obvious Claim 11 and respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

Applicants also assert that Anderson fails to provide any additional knowledge relevant to one of ordinary skill in the art in the area of the present application with regard to the delivery device configuration recited in the claims. For example, Anderson fails to teach or suggest a device retained in the vagina by outward tensioning of the arms, and fails to teach or suggest pods capable of releasing a drug to vaginal mucosal membrane. Accordingly, Applicants assert that, by modifying the device in Hiller with various elements disclosed in Anderson, as proposed by the Examiner on pages 4-5 of the Office Action, one of ordinary skill in the art in the area of the present application would fail to arrive at the devices recited in Claim 3, 9, 14 and 21. Applicants therefore assert that Hiller or Anderson, separately or in combination, fail to render obvious the rejected claims and respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In light of the amendments and the above remarks, Applicants are of the opinion that the Office Action has been completely responded to, and that the application is now in condition for allowance. Such action is respectfully requested.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404)815-6102 is respectfully solicited.

Respectfully submitted,

/elena s. polovnikova/

Elena S. Polovnikova, Ph.D.
Patent Agent
Reg. No. 52,130

KILPATRICK STOCKTON LLP
1100 Peachtree Street
Suite 2800
Atlanta, Georgia 30309-4530
Tele: (404) 815-6500
Docket No.: 42368-350041